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BIOMET

510(k) Summary

FEB - 2 2007

Preparation Date: November 20, 2006

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Susan Alexander

Proprietary Name: Titanium Repicci II® Unicondylar Femoral Knee Components
CoCr Repicci II® Unicondylar Knee

Common Name: Knee femoral

Classification Name: Prosthesis, Knee Femorotibial, Semi-Constrained, Cemented, Metal/Polymer (21 CFR §888.3530)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Titanium Femoral Knee Components (Maxim® and AGC®)	K041466	Biomet, Inc.
Repicci II® Unicondylar Knee System	K020264	Biomet, Inc.
Titanium Femoral Component	K981996	Biomet, Inc.
Repicci II® Unicondylar Knee	K971938	Biomet, Inc.

Device Description:
The Titanium Repicci II® Unicondylar Femoral Knee Components are medial or lateral unicondylar knee replacement implants available in six sizes. Each size is anatomical in nature and is available in two configurations – one for the medial side of right knees and lateral side of left knees (LL/RM), and one for the lateral side of right knees and the medial side of left knees (RL/LM).

The CoCr Repicci II® Unicondylar Knee (K020264) is available in five sizes. Each size is anatomical in nature and is available in two configurations – one for the medial side of right knees and lateral side of left knees (LL/RM), and one for the lateral side of right knees and the medial side of left knees (RL/LM).

Intended Use:
The Titanium Repicci II® Unicondylar Femoral Knee Components and the CoCr Repicci II® Unicondylar Knee are indicated for partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

These devices are single-use implants intended for implantation with bone cement.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE 574.267.6639 ■ FAX 574.267.8137 ■ E-MAIL biomet@biomet.com

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Summary of Technologies: The technological characteristics (material, design and sizing) of the Titanium Repicci II® Unicondylar Femoral Knee Components and the CoCr Repicci II® Unicondylar Knee Components are similar or identical to the predicate devices. The indications are exactly the same as the predicate Repicci II® Unicondylar knee systems.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Manufacturing Corp.
% Ms. Susan Alexander
Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

FEB - 2 2007

Re: K063515
Trade/Device Name: Titanium Repicci II® Unicondylar Femoral Knee Components and CoCr Repicci II® Unicondylar Knee Components
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HRY
Dated: November 20, 2006
Received: November 21, 2006

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

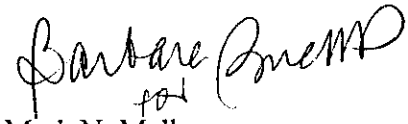
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063515

Device Name: Titanium Repicci II® Unicondylar Femoral Knee Components
CoCr Repicci II® Unicondylar Knee

Indications For Use:

The Titanium Repicci II® Unicondylar Femoral Knee Components and CoCr Repicci II® Unicondylar Knee are indicated for partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

These devices are single-use implants intended for implantation with bone cement.

Prescription Use ___X___ AND/OR Over-The-Counter Use __NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063515